1.3 510(k) Summary

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

CoaguSense, Inc.
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Contact:
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Regulatory Affairs

Date Prepared: January 18, 2010

NAME OF DEVICE

Trade Name: CoaguSense Self-Test PT/INR Monitoring System
Common Name: Prothrombin Time Test
Classification Name: Prothrombin Time Test

Regulation Number	Product Code	Classification Name	Device Class
864.7750	GJS	Prothrombin Time Test	II

PREDICATE DEVICES

- Immedia™ Prothrombin Time System (Farallon Medical, Inc.): #K050243
- INRatio PT Self-Test Monitoring System (HemoSense, Inc.): #K021923
- INRatio 2 PT Self-Test Monitoring System (HemoSense, Inc.): #K072727
- CoaguChek™ PT-S Test (Roche Diagnostics, Inc.): #K030845

DEVICE DESCRIPTION

The CoaguSense Self-Test PT/INR Monitoring System is a portable medical device for the measurement of the Prothrombin Time (PT) using fresh capillary whole blood obtained from a finger prick. The test is performed by inserting a test strip into the meter and applying a drop of blood to the sample receptacle of the test strip. The meter automatically performs the PT test and the result is displayed as International Normalized Ratio (INR) and seconds (PT).

The meter automatically stores all test results in memory. The device is powered by batteries or AC adapter. The disposable strip contains a rotating, spoked wheel that draws the sample into the reaction well after it is applied to the sample receptacle. The spokes rotate across the path of an infrared light beam and mix the liquid sample with the thromboplastin which is dried in the reaction well. When the sample clots, the clot is picked up by the spokes, interrupting the path of the infrared light beam that is detected by the meter. A bar code on each test strip conveys calibration and lot information. A control strip is also provided for quality control purposes.

INDICATION FOR USE STATEMENT

The CoaguSense Self-Test PT Monitoring System is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and international normalized ratio (INR) units. It uses fresh capillary whole blood. It is intended for use by properly selected and suitably trained patients or their caregivers on the order of the treating doctor. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self-testing with the CoaguSense Self-Test PT Monitoring System. It is not intended to be used for screening purposes.

SUBSTANTIAL EQUIVALENCE COMPARISON

The CoaguSense Self-Test PT/INR Monitoring System is substantially equivalent in technology, features, design, materials and intended use to other cleared medical device products that measure Prothrombin Time in human blood. This device is the identical mechanical device to the Immedia™ PT System, that was cleared in #K050243, but the labeling has been changed for physician-directed, self-test use by patients. The INRatio and CoaguChek PT-S PT/INR meters are also cleared for self testing by patients.

PERFORMANCE TESTING

Verification and validation testing activities were conducted to establish the performance, functionality and reliability characteristics of CoaguSense Self-Test PT/INR Monitoring System.

Testing included electrical safety, environmental testing, system testing, impact testing, and functional testing. A hazard and software risk analysis also was performed with associated risks mitigated through design or labeling.

The CoaguSense Self-Test PT/INR Monitoring System was tested under conditions of actual use at clinical sites and in patient's homes to validate that the system performed as intended and met the users' expectations. Over 100 patients performed a self-test at home every 3-4 days over a 10-week period. The study compared CoaguSense PT/INR test results obtained by the patient to those obtained by the healthcare practitioner (HCP). The study results demonstrated that the lay patient user with no laboratory training can be trained to use the CoaguSense Self-Test PT/INR Monitoring System to obtain results that are comparable to results obtained by the health care professional. Results obtained by the trained users and the

HCPs produced a correlation of 0.98. The precision obtained by users on the CoaguSense device was an overall average CV% of 3.48% for subjects and 2.52% for HCPs. The CoaguSense Self-Test PT/INR Monitoring System performs as designed and intended in the hands of lay users.

CONCLUSION

CoaguSense Self-Test PT/INR Monitoring System is substantially equivalent in technology, features, and indications for use to devices cleared under the Federal Food, Drug and Cosmetic Act. The device has the same fundamental scientific technology and intended use as the predicate devices. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

CoaguSense, Inc.
c/o Mr. Douglas Patterson
Chief Executive Officer
42840 Christy Street, Suite 110
Fremont, CA 94538

APR 07 2010

Re: k093243
Trade/Device Name: CoaguSense Self-Test Prothrombin Time/INR Monitoring System
Regulation Number: 21 CFR §864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: March 2, 2010
Received: March 4, 2010

Dear Mr. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): #K093243

Device Name: CoaguSense Self-Test PT/INR Monitoring System

Indications for Use:

The CoaguSense Self-Test PT Monitoring System is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and international normalized ratio (INR) units. It uses fresh capillary whole blood. It is intended for use by properly selected and suitably trained patients or their caregivers on the order of the treating doctor. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self-testing with the CoaguSense Self-Test PT Monitoring System. It is not intended to be used for screening purposes.

Prescription Use ☑ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093243